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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,078	04/07/2006	Jan Bastiaan Bouwstra	0807620.00112	2404

545 7590 07/01/2010

IP Patent Docketing
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EXAMINER	
KIM, YUNSOO	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
07/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,078	BOUWSTRA ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/8/10*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,15,17-22 and 26* is/are pending in the application.

4a) Of the above claim(s) *11,12,15 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,18-22 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-12, 15, 17-22 and 26 are pending.

Claims 11, 12, 15 and 17 stand withdrawn from further consideration by the examiner under 37CFR 1.142(b) as being drawn to a nonelected invention.

Accordingly, claims 1-10, 18-22 and 26, drawn to a method of preventing crystallization of recombinant or synthetic gelatin of a vaccine composition are under consideration in the instant application.

2. The following rejection remains.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-10, 18-22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/34801 (IDS reference, of record) in view of Greiff et al. (Applied Microbiology, 1970, vol. 20, p. 935-938, of record) for the reasons set forth in the office action mailed on 10/9/09.

The '801 publication teaches a method of producing a vaccine formulation comprising an antigen and a recombinant gelatin (p. 86, claims 39, 1, 18-19) and the vaccine formulation is lyophilized (p. 66-67). The '801 publication further teaches that the molecular weight of gelatin includes 10 to 30kDa and about 8kDa or 9KDa (p. 8, lines 10-15).

Note that the referenced vaccine composition comprising a gelatin and antigen is dry and powder (claims 18-19) after lyophilization. Moreover, the '801 publication teaches that the recombinant gelatin is homogenous (p. 40), claim 2 reciting "homodisperse" ,which means at least 90% of gelatin has molecular weight lies within +/- 10% around the selected molecular weight (specification 10), and claim 5 and 20 reciting "optimally aligned by GAP" are included in this rejection (p.17-18, overlapping paragraph).

Given that gelatin cannot be reconstituted if lyophilized as gel and the referenced vaccine is reconstituted, claim 25 reciting "lyophilized gelatin in the sol state" is included in this rejection.

The disclosure of the '801 publication differs from the claimed invention in that it does not teach reducing and maintaining water content to be below 2 weight percent as is recited in claims 1 and 16 of the instant application.

Greiff teaches that the lyophilization of influenza virus and the moisture content of 1.6% after lyophilization found best for stabilization of vaccine composition without affecting the efficacy of the vaccine (abstract, Table 3, discussion). Greiff further teaches that the time of lyophilization is related to percent residual moisture (e.g. 28 hrs for 1.5% residual moisture, 48 hrs for 0.6 % residual moisture and 20 hrs for 3% residual moisture, respectively, p. 935, 2nd col.).

Claim 8 is included in this rejection because having "the water content below 2% " expects to prevent crystallization of the recombinant gelatin for at least 7 years upon lyophilization of

vaccine to the water content to 1.6%. Further, claims 9-10 and 21-22 are included in this rejection because preparations are packaged in special vials under vacuum and under gas (p.935).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to reduce water content to 1.6% (e.g. below 2%) as taught by Greiff in the method of making vaccine comprising gelatin as taught by the '801 publication.

One of ordinary skill in the art would have been motivated to do so because the reducing water content to 1.6% increased the stability of vaccine composition of the order of years as compared to the other test compositions and the dryness of the composition is time dependent and be monitored.

From the teachings of references, it would have been obvious to one of ordinary skill in the art to combine the teachings of the references and there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time of invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 4/8/10 have been fully considered but they were not persuasive.

Applicant has asserted that there is no reasonable expectation of success to combine the references. Applicant has further asserted that the Greiff reference does not result in the reduction of residual moisture to claimed "below 2%". Applicant has asserted that the final moisture content taught by the Greiff reference is 2.8% and there is no motivation to combine the reference.

Contrary to Applicant's assertion, the Greiff reference teaches that the lyophilization for 48 hours results in 0.5% of residual moisture while the lyophilization for 20 hours results in 2.8% of residual moisture (p. 935). Note that the reference further teaches the content of residual moisture of 1.7% provides the maximum stability (p. 938). As discussed above, it would have

been obvious to one of ordinary skill in the art at the time the invention was made to reduce water content to 1.6% (e.g. below 2%) as taught by Greiff in the method of making vaccine comprising gelatin as taught by the '801 publication. Therefore, the combination of the references remains obvious and the rejection is maintained.

5. No claims are allowable.

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F,9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
June 22, 2010

/Michael Szperka/
Primary Examiner, Art Unit 1644